

56. (previously presented) A method for preparing a tablet for the vaginal administration of progesterone for systemic use, comprising:

(i) mixing water with micronized progesterone to obtain wetted micronized progesterone in the absence of any other ingredient; and

drying said wetted micronized progesterone to form dry micronized progesterone;

(ii) mixing said dry micronized progesterone with

(a) a pharmaceutically acceptable non effervescent excipient or diluent and

(b) an effervescent to form a mixture; and

(iii) forming a tablet by direct compaction of said mixture.

57. (previously presented) A method according to claim 56 for preparing a tablet for the vaginal administration of progesterone for systemic use, wherein the step of mixing said dry micronized progesterone with (a) a pharmaceutically acceptable non effervescent excipient or diluent and (b) an effervescent comprises:

(i) sieving a first lubricant to obtain a sieved first lubricant;

(ii) mixing said dry micronized progesterone with said sieved first lubricant and a material selected from a first filler or a disintegrant to form a first mixture;

(iii) mixing a binder which binds dry particles with said first mixture to form a second mixture;

(iv) intimately mixing said effervescent and a first quantity of a second filler to form a third mixture;

(v) sieving said third mixture to obtain a sieved third mixture, and then intimately mixing said sieved third mixture and said second mixture to form a fourth mixture;

(vi) intimately mixing said fourth mixture with a second quantity of said second filler to form a fifth mixture;

(vii) sieving a second lubricant and a material selected from a saponificant or a third lubricant to obtain, respectively, sieved second lubricant and sieved third lubricant; and

(viii) intimately mixing said sieved second lubricant and said sieved third lubricant with said fifth mixture to form a sixth mixture.

58. (previously presented) A method according to claim 57, wherein said first lubricant is sieved through sieves having a pore size of between about 400 and 450 microns.

59. (previously presented) A method according to claim 58, wherein said first lubricant is sieved through sieves having a pore size of about 425 microns.

60. (previously presented) A method according to any of claim 57, wherein said third mixture is sieved through sieves having a pore size of between about 400 and 450 microns.

61. (previously presented) A method according to any of claim 58, wherein said third mixture is sieved through sieves having a pore size of between about 400 and 450 microns.

62. (previously presented) A method according to any of claim 59, wherein said third mixture is sieved through sieves having a pore size of between about 400 and 450 microns.

63. (previously presented) A method according to claim 60, where said pore size is about 425 microns.

64. (previously presented) A method according to claim 61, where said pore size is about 425 microns.

85. (previously presented) A method according to claim 57, wherein said material selected from a saponificant or a third lubricant is sodium lauryl sulfate.

86. (previously presented) A method according to claim 56, wherein said effervescent is a mixture of a pharmaceutically acceptable carboxylic or dicarboxylic acid and a pharmaceutically acceptable salt of HCO_3 .

87. (previously presented) A method according to claim 86, wherein said pharmaceutically acceptable carboxylic or dicarboxylic acid is selected from adipic acid or tartaric acid.

88. (previously presented) A method according to claim 86, wherein said pharmaceutically acceptable salt of HCO_3 is as sodium bicarbonate.

89. (previously presented) A method according to claim 86, wherein said pharmaceutically acceptable carboxylic or dicarboxylic acid and said bicarbonate are present in an amount providing a molar excess of COOH groups.

90. (previously presented) A method according to claim 86, wherein said effervescent comprises a mixture of adipic acid and sodium bicarbonate.

91. (previously presented) A method according to claim 56, wherein said effervescent comprises between about 6 and 10 wt.%.

92. (previously presented) A method according to claim 55 wherein the amount of water mixed with said micronized progesterone is between about 25 and 28 wt.% of the amount of micronized progesterone.

93. (previously presented) A method according to claim 92, wherein the amount of water mixed with said micronized progesterone is about 28 wt.% of the amount of micronized progesterone.

94. (previously presented) A method according to claim 55, wherein said water is added to said micronized progesterone at rate of between about 6 to 9 ml per minute.

95. (previously presented) A method according to claim 55, wherein said water is mixed with said micronized progesterone at a mixing speed of between about 25 33.3 rpm.

96. (previously presented) A method according to claim 55, wherein said drying of said wetted micronized progesterone is done at a temperature of between about 55°C and about 60°C.

97. (previously presented) A method according to claim 55, wherein all of said mixing steps are carried out at a temperature of between about 15°C and 30°C.

98. (canceled)

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100. (previously presented, allowed) A tablet prepared by the steps of:

(a) a pharmaceutically acceptable non effervescent excipient or diluent and

(b) an effervescent to form a mixture; and

(iii) forming a tablet by direct compaction of said mixture,

the tablet having a T_{max} upon disintegration of at least about three hours;

and retaining said tablet in said vagina for a time efficacious to deliver said progesterone to said patient.

107. (previously presented) A method according to claim 106, wherein said tablet contains at least 50 mg of micronized progesterone.

108. (previously presented) A method according to claim 106, wherein said placing of tablet is effected as part of a twice daily dosing regimen.

109. (previously presented) A method for preparing a tablet for vaginal administration which comprises

(i) mixing water with micronized progesterone to obtain wetted micronized progesterone prior to adding any other ingredients; and

drying said wetted micronized progesterone;

(ii) mixing a pharmaceutically acceptable excipient or diluent with said micronized progesterone after said drying to form a tableting mixture; and

(iii) directly compacting said tableting mixture to form said tablet.

110. (previously presented) A method for preparing a tablet for the vaginal administration of progesterone for systemic use, comprising the steps of:

